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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,091	02/01/2002	Marshall D. Crew	PC23132A	7361

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/05/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,091

Applicant(s)

MARSHALL D. CREW

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-25 is/are allowed.
- 6) ☒ Claim(s) 26-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Examiner acknowledges receipt of IDS filed 06/18/03 and 07/03/03, request for extension of time and response to election restriction requirement.

Election/Restrictions

Applicants elected Group I with traverse on the grounds that there is no burden on the examiner to examine the Groups I, II and III together because Groups I, II and III are classified in the same class and subclass. Applicants further requested that Groups I, II and III be examined together. Upon further consideration, examiner agrees with applicants regarding Groups I, II and III.

Secondly, election requirement is directed to Group IV where more than one composition is claimed. An election is required for group IV where many compositions are claimed as it regards to the cholesteryl ester transfer protein inhibitor.

The method of claims 1, 6 and 13 are free of art and are thus allowable. However, examination is extended to Group IV and claims 26-42 are addressed below. An election is also required.

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.

Applicants are respectfully requested to provide art that are pertinent to the invention.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 26-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Sikorski (WO 99/14204 cited by applicants in the disclosure and on the IDS filed 07/30/01).

Sikorski teaches a composition comprising cholesteryl ester transfer protein (CETP) inhibitor (page 4, line 30 to page 12 and line 19) and one or more non-toxic pharmaceutically acceptable carriers (page 80, line 4). On page 84, lines 27-29, Sikorski teach that CETP inhibitors are formulated as dispersions in hydroxypropylmethyl cellulose. Solutions and suspensions of the formulation can be prepared from sterile powders (page 84, lines 32 and 33). The active compound, which is the cholesteryl ester transfer protein inhibitor can be combined with one or more adjuvants and cellulose alkyl esters and polyvinylpyrrolidone are examples (page 84, lines 16-32). The formulation of Sikorski can be administered orally, intravascularly, intraperitoneally, subcutaneously, intramuscularly, topically (page 80, lines 11-14) and also to the eye (page 84, lines 8-15). The compounds of Sikorski, the CETP's, are useful for human treatment, veterinary treatment, exotic and farm animal treatment (mammals, rodents, horses, dogs and cats) and the CETP's are useful in the treatment of dyslipidemia, coronary artery disease, atherosclerosis and coronary artery diseases (page 6, lines 2-20). Sikorski also discloses how to measure CETP activity *in Vitro* (page 71, line 14 to page 72 line 21) and inhibition of CETP activity is also tested *in Vivo* (page 72, line 23 to page 74 line 13).

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Properties of the composition are recited in claims 31-37 and the property of a composition is not separable from the composition. Thus, Sikorski meets the limitations of the claims.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: Many cholesteryl ester transfer protein inhibitors are claimed in compositions resulting in many compositions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 26 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.


Blessing Fubara
Patent Examiner
Tech. Center 1600